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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/735,014

12/12/2003

Audrey Goddard

10466/486

2599

7590 02/07/2007
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EXAMINER

CHANDRA, GYAN

ART UNIT

PAPER NUMBER

1646

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/735,014

Applicant(s)

GODDARD ET AL.

Examiner

Gyan Chandra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

Claims 22-26 are pending and are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Claim Rejections - 35 USC § 101 & 35 USC § 112

The rejection of claims 22-26 under 35 U.S.C. § 101 is maintained for the reasons of record as set forth in the office action mailed on 6/13/2006.

The rejection of claims 22-26 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in the office action mailed on 6/13/2006.

The instant claims are drawn to an isolated antibody that binds to the polypeptide of SEQ ID NO: 83 and that the antibody is a monoclonal or humanized antibody. The claims also recite that the antibody is labeled.

Applicants reiterate their arguments (page 3 of Response) that Example 34 of the instant specification discloses that the PRO361 polypeptide tested positive in the Mixed Lymphocyte Reaction (MLR) Assay. Applicants argue that the MLR assay is art recognized for identifying molecules which suppresses an immune response. Applicants argue (page 5 of Response) that the MLR assay described in the present specification is a comparative assay, meaning that the utility of PRO361 demonstrated by this assay is based upon a comparison of relative expression levels between a known molecule

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and the unknown PRO361 molecule. Applicants argue that the difference in response between known molecule and unknown molecule in the MLR assay could provide useful information. Applicants argue that the USPTO is behaving like the FDA for asking data in support of utility. On page 6 of Response, Applicants argue that the instant specification establishes a utility of PRO361 by disclosing that the polypeptide PRO361 is positive in the MLR assay. Therefore, the polypeptide is useful as an immunosuppressive agent. Applicants argue that the Fong declaration details the state of the art in the field of immunostimulation/suppression.

Applicants' arguments have been fully considered but they are not persuasive because the mixed lymphocyte culture (MLC or also known as MLR) is a special case of antigen stimulation in which T lymphocytes respond to foreign histocompatibility antigen on unrelated lymphocytes or monocytes. The art does recognize that the MLR assay is useful in screening a compound that could have a role in immune response (see previous office action, pg.4). However, Applicants' assertions that the claimed invention could be useful for the treatment of conditions because the specification at page 141, lines 33-35, states " any decreases below control is considered to be a positive result for an inhibitory compound, with decreases of less than or equal to 80% being preferred" are not persuasive. The ability of the claimed protein to stimulate or inhibit lymphocyte proliferation in the MLR assay does not provide support for what specific conditions or for which specific diseases the claimed invention would predictably function for a therapeutic suppression of the immune system. Therefore, the results of the MLC or MLR assay in the instant specification are merely preliminary and do not

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support a specific and substantial utility for the claimed invention. Further, one of ordinary skill in the art would not conclude that a molecule which tested positive in the assay (page 141 of the specification) wherein "any decreases below control is considered to be a positive result for an inhibitory compound" would be useful as a molecule in preventing suppression of immune response in an individual (asserted use). There is insufficient data presented to conclude anything regarding the ability of an antibody that binds to the polypeptide PRO361 of the invention to be used in a substantial way to therapeutically inhibit an immune response, and much more experimentation would be required to use the invention in this manner. Further, in response to Applicants' arguments regarding the Fong's declaration, the Examiner has fully considered but are not persuasive for the reasons of record in pages 4-6 of 11/1/2005 office action.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra, Ph.D.
Art Unit 1646
29 January 2007
Fax: 571-273-2922


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SUPERVISORY PATENT EXAMINER
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